IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

UNITED STATES OF AMERICA, et al. ex rel. CIMZNHCA, LLC, Plaintiff, v. UCB, INC.; RXC ACQUISITION COMPANY d/b/a RX CROSSROADS; OMNICARE, INC.; and CVS HEALTH CORPORATION, Defendants.	)	Case No.: 3:17-cv-00765-SMY-DGW

FIRST AMENDED COMPLAINT AND JURY DEMAND

PRELIMINARY STATEMENT

Plaintiff-Relator CIMZNHCA, LLC ("CIMZNHCA" or "Relator"), through its undersigned attorneys, alleges, based upon personal knowledge, relevant documents, investigations and information and belief, as follows:

1. This is a civil action brought against Defendant UCB, Inc. ("UCB"), and Defendants RXC Acquisition Company (*d/b/a* RXCrossroads), Omnicare, Inc., and CVS Health Corporation (collectively referred to as "RXC") on behalf of the Government under the False Claims Act, 31 U.S.C. §§ 3729-3733 (the "False Claims Act" or "FCA) and the false claims acts of the respective Plaintiff States[1] to recover treble damages sustained by, and civil penalties and

[1] The state statues are the: (1) California False Claims Act, Cal. Gov't Code §§ 12650 – 12656; (2) Colorado Medicaid False Claims Act, Colo. Rev. Stat. Ann. §§ 25.5-4-303.5 – 4-310; (3) Connecticut False Claims and Other Prohibited Acts Under State-Administered Health or Human Services Programs Act, Conn. Gen. Stat. Ann. §§ 4-274 – 289; (4) Delaware False Claims and Reporting Act, Del. C. Ann. tit. 6, §§ 1201 – 1211; (5) District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act of 2012, D.C. Code Ann. §§ 2-381.01 – 381.10; (6) Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 – 68.092; (7) Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 – 4-168.6; (8) Hawaii False Claims to the State Act, Haw. Rev. Stat. Ann. §§ 661-21 – 31; (9) Illinois False Claims Act, 740 Ill. Comp. Stat. Ann. §§ 175/1 – 175/8; (10) Indiana False Claims and Whistleblower Protection Act, Ind. Code Ann. §§ 5-11-5.5-1 – 5.5-18; (11) Iowa False Claims Act, Iowa Code Ann. §§ 685.1 – 685.7; (12) Louisiana Medical Assistance Programs Integrity Law, La. Stat. Ann. §§ 437.1 – 440.16; (13) Massachusetts False Claims Law,

restitution owed to, the United States Government and the respective state governments as a result of two intertwined, unlawful drug marketing schemes.

2. Since at least 2011, through the implementation of two different schemes, UCB and RXC have provided remuneration in the form of free services to prescribing providers in order to induce those providers to prescribe UCB's drug, Cimzia, to patients—a more typical unlawful "quid pro quo" kickback scheme. As a result of these schemes, pharmacies have submitted and continue to submit claims to Medicare and Medicaid that were tainted by kickbacks, causing these programs to pay tens of millions of dollars in improper reimbursements. These schemes are ongoing.

3. UCB and RXC's schemes undermine the independent decision making of providers, an important element in Government Healthcare Program coverage policy. The providers prescribing UCB's drug, Cimzia, did not necessarily do so because they believed, based on their medical judgment, review of peer-reviewed medical literature, or discussion with their colleagues, that the drug would help their patients. Rather, UCB's drug, Cimzia, was and often is supplied because UCB and RXC actively and improperly pursued and enticed providers with free services and other forms of remuneration.

4. As a result of these schemes, pharmacies have submitted and continue to submit

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Mass. Gen. Laws Ann. ch. 12, §§ 5A – 5O; (14) Michigan Medicaid False Claim Act, Mich. Comp. Laws Ann. §§ 400.601 – 615; (15) Minnesota False Claims Act, Minn. Stat. Ann. §§ 15C.01 – 16; (16) Montana False Claims Act, Mont. Code. Ann. §§ 17-8-401 – 416; (17) Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. §§ 357.010 – 357.250; (18) New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 – 32C-18; (19) New Mexico Medicaid False Claims Act, N.M. Stat. Ann.§§ 27-14-1 – 14-15; (20) New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 – 9-14; (21) New York False Claims Act, N.Y. Fin. Law §§ 187 – 194; (22) North Carolina False Claims Act, N.C. Gen. Stat. Ann. §§ 1-605 – 618; (23) Oklahoma Medicaid False Claims Act, Okl. Stat. Ann. tit. 63, §§ 5053 – 5054; (24) Rhode Island State False Claims Act, R.I. Gen. Laws Ann. §§ 9-1.1-1 – 9; (25) Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101 – 108; (26) Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 – 185; (27) Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 – 36.132; (28) Virginia Fraud Against Tax Payers Act, Va. Code Ann. §§ 8.01-216.1 – 216.19; and (29) Washington Medicaid Fraud False Claims Act, Wash. Rev. Code Ann. §§ 74.66.005 – 74.66.130.

claims to Medicare and Medicaid that were tainted by kickbacks, causing these programs to pay tens of millions of dollars in improper reimbursements.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the claims Relator brings on behalf of the United States under the FCA pursuant to 28 U.S.C. §§ 1331 and 1345. This Court has supplemental jurisdiction over the claims asserted under the laws of the State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the District of Columbia, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Iowa, the State of Louisiana, the Commonwealth of Massachusetts, the State of Michigan, the State of Minnesota, the State of Montana, the State of Nevada, the State of New Jersey, the State of New Mexico, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the Commonwealth of Virginia, and the State of Washington, pursuant to 28 U.S.C. § 1367(a) and 31 U.S.C. § 3732(b).

6. This Court may exercise personal jurisdiction over UCB and RXC and venue is proper in this District pursuant to 31 U.S.C. § 3732(a) as well as 28 U.S.C. §§ 1391(b) and 1391(c) because UCB and RXC each transact business in this District and, in furtherance of its fraudulent kickback schemes, caused to be submitted or conspired to submit false claims in this District.

7. Relator has direct and independent knowledge on which the allegations herein are based, is an original source of this information, and has voluntarily provided the information to the United States before filing this action based on the information known to Relator. This suit is not based on prior public disclosures of allegations or transactions in a criminal, civil or administrative hearing, lawsuit, investigation, audit or report, or from the news media. To the extent that there has been any public disclosure unknown to Relator, Relator is an original source

under 31 U.S.C. § 3730(e)(4) and the applicable provisions of the respective State False Claims Act laws.

PARTIES

8. Relator CIMZNHCA, LLC ("CIMZNHCA") is a New Jersey-based entity formed to investigate and act as the Relator for the matters alleged herein.

9. Relator brings this action on behalf of the United States pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3729 *et seq.*

10. Defendant UCB, Inc. ("UCB") is a human therapeutics company in the biotechnology industry. It conducts business throughout the United States, including the Southern District of Illinois, and in many other countries. Defendant UCB is incorporated in the State of Delaware and has its United States headquarters in Smyrna, Georgia with its principal place of business located at 1950 Lake Park Drive, Smyrna, Georgia 30080. Defendant UCB engages in the discovery, development, manufacture, and delivery of bio-therapeutics (e.g., prescription drugs) for various medical needs. Defendant UCB's drugs include the drug, Cimzia.

11. Defendant RXC Acquisition Company (*d/b/a* RXCrossroads) is a Delaware corporation headquartered in Kentucky with its principal place of business located at 1901 Eastpoint Parkway, Louisville, Kentucky, 40223. In 2005, Defendant RXC Acquisition Company (*d/b/a* RXCrossroads) was acquired by Defendant Omnicare, Inc. Later, in 2015, Defendant RXC Acquisition Company (*d/b/a* RXCrossroads) and Defendant Omnicare, Inc. were acquired by Defendant CVS Health Corporation. Defendant RXC Acquisition Company (*d/b/a* RXCrossroads) provides and coordinates services between wholesale distributors, home health agencies, nurse educators, pharmacies, and health care product manufacturers, including UCB. It conducts business throughout the United States, including the Southern District of Illinois.

12. Defendant Omnicare, Inc. ("Omnicare") is a Delaware corporation headquartered in Cincinnati, Ohio with its principal place of business located at Omnicare, Inc. 900, Omnicare Center 201, East Fourth Street, Cincinnati Ohio, 45202. Defendant Omnicare purchased Defendant RXC Acquisition Company (*d/b/a* RXCrossroads) in 2005. Defendant Omnicare is a wholly owned subsidiary of Defendant CVS Health Corporation and provides comprehensive pharmaceutical services to patients and providers across the United States, including the Southern District of Illinois.

13. Defendant CVS Health Corporation ("CVS") is Delaware corporation headquartered in Woonsocket, Rhode Island with its principal place of business located at One CVS Drive, Woonsocket, Rhode Island 02895. Defendant CVS acquired Defendant RXC Acquisition Company (*d/b/a* RXCrossroads) and Defendant Omnicare in 2015. Defendant CVS is the largest pharmacy health care provider in the United States, with integrated offerings across the spectrum of pharmacy care. It conducts business throughout the United States, including the Southern District of Illinois.

14. Defendant RXC Acquisition Company (*d/b/a* RXCrossroads), Defendant Omnicare, and Defendant CVS are collectively referred to herein as "Defendant RXC" and/or "RXC."

15. Defendant UCB and Defendant RXC are collectively referred to herein as "Defendants."

STATUTORY BACKGROUND

A. The False Claims Act

16. The FCA establishes treble damages liability to the United States for any individual or entity that:

> knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
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> knowingly makes or uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or
>
> conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

31 U.S.C. § 3729(a)(1)(A)-(C). Within the meaning of the FCA, "knowing" is defined to include reckless disregard and deliberate indifference. *Id*.

17. In addition to treble damages, the FCA also provides for assessment of a civil penalty for each violation or each false claim. The civil penalties range from (a) $5,500 to $11,000 for violations that occurred prior to November 2, 2015; (b) $10,781 to $21,563 for violations that occurred from November 3, 2015 to February 2, 2017; and (c) $10,957 to $21,916 for violations that occurred after February 3, 2017. *See, e.g.,* 64 Fed. Reg. 47099, 47103 (1999).

B. The Anti-Kickback Statute

18. The Anti-Kickback Statute, 42 U.S.C. §1320a-7b *et seq.* ("AKS"), states as follows in relevant part:

> (b) Illegal remunerations
>
> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
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> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

19. For purposes of the AKS, "remuneration" includes the transfer of anything of value, in cash or in-kind, directly or indirectly, covertly or overtly. Importantly, the AKS has been interpreted to cover any arrangement where one purpose of the remuneration is to obtain money for referral of services or to induce further referrals.

20. The AKS is designed to, among other things, ensure that patient care will not be improperly influenced by inappropriate compensation from the pharmaceutical industry.

21. In order to ensure compliance, every federally-funded health care program requires every provider or supplier to ensure compliance with the provisions of the AKS and other federal laws governing the provision of health care services in the United States.

22. The AKS was amended in March 2010 as part of the Patient Protection and Affordable Care Act ("PPACA"), which clarified that all claims resulting from a violation of the AKS are also a violation of the FCA. 42 U.S.C. § 1320a-7(b)(g). The PPACA also amended the

Social Security Act's "intent requirement" to make clear that violations of its anti-kickback provisions, like violations of the FCA, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation." 18 U.S.C. § 1347(b).

23. Knowingly providing kickbacks to providers to induce them to prescribe a drug (or to influence provider prescriptions) for individuals who seek reimbursement for the drug from a federal health care program or causing others to do so, while certifying compliance with the AKS (or while causing another to so certify), or billing the government as if in compliance with these laws, violates the FCA.

24. The Balanced Budget Act of 1997 amended the AKS to include administrative civil penalties of $50,000 for each violation, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited or received, without regard to whether a portion of that amount was offered, paid or received for a lawful purpose. *See* 42 U.S.C. § 1320a-7a(a).

25. The AKS contains statutory exceptions and certain regulatory "safe harbors" that exclude certain types of conduct from the reach of the statute. *See* 42 U.S.C. § 1320a-7b(b)(3). None of the statutory exceptions or regulatory safe harbors protect the Defendants from liability for the conduct alleged herein. Compliance with the AKS is a condition of payment under federal health care programs.

AFFECTED HEALTH PROGRAMS

26. Generally, when a physician prescribes a drug, a patient is provided with a prescription that is then filled at a pharmacy. The pharmacy then submits the claim for payment to the relevant federal health care program(s) for reimbursement.

27. In certain circumstances, a federal program may also have pharmacy facilities that directly dispense prescription drugs. In such cases, the federal health care program purchases the drug directly rather than reimbursing the pharmacy.

A. Medicare

28. Medicare is a federal program that provides federally subsidized health insurance primarily for persons who are sixty-five years old or older or disabled. *See* 42 U.S.C. §§ 1395, *et seq*. ("Medicare Program"). Part D of the Medicare Program was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, to provide prescription drug benefits for Medicare beneficiaries. Medicare Part D became effective January 1, 2006. All persons enrolled in Medicare Part A and/or Medicare Part B are eligible to enroll in a prescription drug plan under Part D. The United States Department of Health and Human Services ("HHS"), through its component agency, the Centers for Medicare and Medicaid Services ("CMS"), contracts with private companies (or "Part D sponsors") to administer prescription drug plans. Such companies are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Part D sponsors enter into contracts with many pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans.

29. Generally, after a physician writes a prescription for a patient who is a Medicare beneficiary, that patient can take the prescription to a pharmacy to be filled. When the pharmacy dispenses drugs to the Medicare beneficiary, the pharmacy submits a claim electronically to the beneficiary's Part D sponsor, sometimes through the sponsor's pharmacy benefit manager ("PBM"). The pharmacy receives reimbursement from the sponsor (or PBM) for the portion of the drug cost not paid by the beneficiary. The Part D sponsor is then required to submit to CMS an electronic notification of the drug dispensing event, referred to as the Prescription Drug Event

("PDE"), which contains data regarding the prescription claim, including the service provider of the drug, the prescriber of the drug, the quantity dispensed, the amount it has paid to the pharmacy, and whether the drug is covered under the Medicare Part D benefit.

30. Payments to a Part D Plan sponsor are conditioned on the provision of information to CMS that is necessary for CMS to administer the Part D program and make payments to the Part D Plan sponsor for qualified drug coverage. 42 C.F.R. § 423.322. CMS's instructions for the submission of Part D prescription PDE claims data state that "information . . . necessary to carry out this subpart" includes the data elements of a PDE. PDE records are an integral part of the process that enables CMS to administer the Part D benefit. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program.

31. CMS gives each Part D sponsor advance monthly payments consisting of the Part D sponsor plan's direct subsidy per enrollee (which is based on a standardized bid made by the Part D sponsor), estimated reinsurance subsidies for catastrophic coverage, and estimated low income subsidies. 42 C.F.R. §§ 423.315, 423.329. At the end of the payment year, CMS reconciles the advance payments paid to each Part D sponsor with the actual costs the sponsor has incurred. In this reconciliation process, CMS uses the PDE claims data it has received from the Part D sponsor during the prior payment year to calculate the costs the Part D sponsor has actually incurred for prescriptions filled by Medicare beneficiaries under Part D. If CMS underpaid the sponsor for low-income subsidies or reinsurance costs, it will make up the difference. If CMS overpaid the sponsor for low-income subsidies or reinsurance costs, it will recoup the overpayment from the sponsor. After CMS reconciles a plan's low-income subsidy and reinsurance costs, it then

determines risk-sharing amounts owed by the plan to CMS or by CMS to the plan related to the plan's direct subsidy bid. Risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs exceeded or fell below a target amount for the plan by certain threshold percentages. 42 C.F.R.§ 423.336.

32. CMS's payments to the Part D sponsor come from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R.§ 423.315(a).

33. In order to receive Part D funds from CMS, Part D Plan sponsors, as well as their authorized agents, employees, and contractors (including pharmacies), are required to comply with all applicable federal laws, regulations, and CMS instructions.

34. By statute, all contracts between a Part D Plan sponsor and HHS must include a provision whereby the Plan sponsor agrees to comply with the applicable requirements and standards of the Part D program as well as the terms and conditions of payment governing the Part D program. 42 U.S.C. § 1395w-112.

35. Medicare Part D Plan sponsors must also certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse, including the FCA and AKS. 42 C.F.R.§ 423.505(h)(l).

36. In accordance with these express statutory and regulatory requirements, all contracts entered into between CMS and Plan D Plan sponsors from 2006 through the present include a provision in which the sponsor "agrees to comply with . . . federal laws and regulations designed to prevent . . . fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. §§ 3729, *et seq*.), and the anti-kickback statute (§ 1127B(b) of the Act)."

37. CMS regulations further require that all contracts between Part D Plan sponsors and downstream entities, such as pharmacies and PBMs, contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(4)(iv).

38. A Part D Plan sponsor also is required by federal regulation to certify to the accuracy, completeness and truthfulness of the PDE claims data submitted to CMS. Specifically, the relevant regulatory provision, entitled "Certification of data that determine payment", provides in relevant part:

> (1) General rule. As a condition for receiving a monthly payment under subpart G of this part (or for fallback entities, payment under subpart Q of this part), the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.
>
> (2) Certification of enrollment and payment information. The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.
>
> (3) Certification of claims data. The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims

> data it submits under § 423.329(b)(3) (or for fallback entities, under§ 423.87l(f)) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement.

42 C.F.R. § 423.505(k).

39. Compliance with the regulatory requirement that the PDE data submitted to CMS is "true, accurate, and complete" is a condition of payment under the Medicare Part D program to the extent that it involves a violation of the AKS.

40. In accordance with this regulatory requirement, since the Part D program began, Medicare has required each Part D Plan sponsor to sign annually an Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor ("Attestation"). This Attestation states:

> Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and the Medicare Part D Organization(s) listed above, hereafter referred to as the Part D Organization, governing the operation of the contract numbers listed above, the Part D Organization hereby makes the following attestations concerning CMS payments to the Part D Organization:
>
> The Part D Organization attests that based on its best knowledge, information, and belief, the final Prescription Drug Event (PDE) data that have been submitted to and accepted by CMS as of [date] with respect to the Part D plans offered under the above-stated contract(s) for the dates of service of January 1, [prior year] to December 31, [prior year], are accurate, complete, and truthful and reflect all retroactive adjustments of which the Part D organization has been informed by May 30, [current year]. In addition, the Part D Organization attests that based on best knowledge, information, and belief, the payments that have been made by the Part D organization for the claims summarized by the aforementioned PDE data were made in accordance with the coordination of benefits guidance in Chapter 14 of the Medicare Prescription Drug Benefit Manual and other applicable CMS guidance. The Part D Organization attests that based on its best knowledge, information, and belief as of the date(s) of last

> successful DIR [Direct and Indirect Remuneration Data] [prior year] data submission(s) via the Health Plan Management System (HPMS) as listed above, the final direct and indirect remuneration data submitted to CMS for the Part D plans offered under the above-stated contract(s) for the [prior] coverage year are accurate, complete, and truthful and fully conform to the requirements in the Medicare Part D program regulations and the Final Medicare Part D DIR Reporting Requirements for [the prior year]. The Part D Organization also certifies that based on its best knowledge, information, and belief as of the date indicated below, all other required information provided to CMS to support the determination of allowable reinsurance and risk corridor costs for the Part D plans offered under the above-stated contract(s) is accurate, complete, and truthful. With regards to the information described in the above paragraphs, the Part D Organization attests that it has required all entities, contractors, or subcontractors, which have generated or submitted said information (PDE and DIR data) on the Part D Organization's behalf, to certify that this information is accurate, complete, and truthful based on its best knowledge, information, and belief. In addition, the Part D Organization attests that it will maintain records and documentation supporting said information. The Part D Organization acknowledges that the information described in the above paragraphs will be used for the purposes of obtaining federal reimbursement and that misrepresentations or omissions in information provided to CMS may result in Federal civil action and/or criminal prosecution.

41. All approved Part D Plan sponsors who received payment under Medicare Part D in benefit years 2006 through the present date submitted these required Attestations in the same or similar format.

42. Medicare regulations further provide: "If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement." 42 C.F.R. § 423.505(k)(3).

43. Medicare also enters into agreements with physicians to establish the physician's eligibility to participate in the Medicare program. For the physician to be eligible for participation in the Medicare program, physicians must certify that they agree to comply with the Anti-Kickback Statute, among other federal health care laws. Specifically, on the Medicare enrollment form, CMS Form 855I, the "Certification Statement" that the medical provider signs states: "You MUST sign and date the certification statement below in order to be enrolled in the Medicare program. In doing so, you are attesting to meeting and maintaining the Medicare requirements stated below." Those requirements include:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me ... The Medicare laws, regulations and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare. I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity

B. Medicaid

44. Medicaid is a joint federal-state program created in 1965 that provides health care benefits for certain groups, primarily the poor and disabled. Each state administers a State Medicaid program. The federal Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A). While drug coverage is an optional benefit, the Medicaid programs of all states provide reimbursement for prescription drugs.

45. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's per capita income compared to

the national average. 42 U.S.C. § 1396d(b). Among the states, the FMAP is at least fifty percent and is as high as eighty-three percent. Federal funding under Medicaid is provided only when there is a corresponding state expenditure for a covered Medicaid service to a Medicaid recipient. The federal government pays to the state the statutorily established share of the "total amount expended ... as medical assistance under the State plan." 42U.S.C. § 1396b(a)(l).

46. The vast majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid programs. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary and determines the amount of federal funding each state will be permitted to draw down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims, including claims from pharmacies seeking payment for drugs, are presented for payment. After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). 42 C.F.R.§ 430.30.

47. Claims arising from illegal kickbacks are not authorized to be paid under state regulatory regimes. In fact, providers who participate in the Medicaid program must sign enrollment agreements with their states that certify compliance with the state and federal Medicaid requirements, including the AKS. Although there are variations among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies furnished.

48. Furthermore, in many states, Medicaid providers, including both physicians and pharmacies, must affirmatively certify compliance with applicable federal and state laws and regulations.

49. For example, in Illinois, physicians and pharmacies must sign an "Agreement for Participation in the Illinois Medical Assistance Program," in which the provider certifies that it is in compliance with applicable federal and state laws and regulations.

C. TRICARE

50. TRICARE (formerly known as CHAMPUS), is part of the United States military's health care system, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel, and military retirees and their dependents. The military health system, which is administered by the Department of Defense ("DOD"), is composed of the direct care system, consisting of military hospitals and military clinics, and the benefit program, known as TRICARE. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations, and fee-for-service benefits.

51. TRICARE prescription drug benefits are provided through three different programs: military treatment facility outpatient pharmacies, TRICARE network retail pharmacies, and TRICARE's mail order service. TRICARE contracts with a PBM to administer its retail and mail order pharmacy programs. In-addition, TRICARE beneficiaries can also pay out-of-pocket to fill prescriptions at non-network retail pharmacies and submit a claim for reimbursement directly with TRICARE's PBM. The claims process is different for each of these pharmaceutical programs.

52. When a TRICARE beneficiary brings a prescription to a TRICARE network retail pharmacy, for example, the pharmacy submits an electronic claim to the PBM for that prescription event. The PBM sends an electronic response to the pharmacy that confirms the beneficiary's TRICARE coverage, and, if the prescription claim is granted, informs the pharmacy of the calculated pharmacy reimbursement amount and the co-pay (if applicable) to be collected from the beneficiary. The pharmacy then collects the co-pay amount (if any) from the beneficiary and dispenses the medication. After a 10-day hold to ensure the prescription was picked up and not returned to the shelf by the pharmacy, the PBM sends a TRICARE Encounter Data ("TED") record electronically to TRICARE. The TED record includes information regarding the prescription event, including the reimbursement amount to be paid to the dispensing pharmacy. TRICARE then authorizes the PBM to make payment to the pharmacy for the amount remaining (after co-pay) on the claim. The PBM sends the payment to the pharmacy. After the payment is made by the PBM's bank, the PBM's bank requests reimbursement from the Federal Reserve Bank ("FRB"). The FRB then transfers funds to the PBM's bank account.

53. If the prescription is filled at a non-network retail pharmacy, the beneficiary must pay the full price of the prescription to the pharmacist and file a claim for reimbursement on DD Form 2642, TRICARE DoD/CHAMPUS Medical Claim -- Patient's Request for Medical Payment ("Form 2642"). The Form 2642 is mailed to the PBM. As in the case of reimbursements under the retail pharmacy program, a TED record is created and sent to TRICARE. TRICARE then authorizes payment to the TRICARE beneficiary. Upon receiving that authorization, the PBM issues a check to the beneficiary, which is drawn on the PBM's bank account. TRICARE then reimburses the PBM in the same manner as it does under the retail pharmacy program, such that funds are transferred from the FRB to the PBM's bank account.

54. TRICARE beneficiaries can also fill prescriptions through TRICARE's mail order pharmacy program as well. TRICARE beneficiaries submit prescriptions by mail, fax, or electronically to TRICARE's PBM, along with any co-pay (if applicable). TRICARE's PBM delivers the prescription to the beneficiary via free standard shipping. The medications dispensed through the mail order pharmacy program are filled from the PBM's existing inventory of pharmaceuticals. The PBM then requests replenishment pharmaceuticals from DOD's national prime vendor contracted by Defense Logistics Agency ("DLA"). DOD procures the pharmaceuticals through its national prime vendor and replenishes the PBM's inventory of pharmaceuticals after accumulated dispensing reach full package size amounts. The PBM then submits a TED record to TRICARE to obtain administrative fees in connection with that prescription event. DLA bills TRICARE directly for drug replenishment costs.

55. Pursuant to 38 U.S. C. § 8126, pharmaceutical manufacturers are required to enter into national contracts with the DOD pursuant to which the manufacturer makes available for procurement certain covered drugs at the Federal Ceiling Price (a price that is calculated as at least 24% less than the manufacturer's average price based on all sales to commercial customers through a wholesaler or distributor). Pursuant to DOD's contract with its national prime vendor, the national prime vendor submits an invoice to the DOD for payment of pharmaceuticals supplied to the PBM in connection with the mail order pharmacy program, charging the DOD the price set by the contract awarded by the DOD to the drug manufacturer.

56. Since March 2003, TRICARE has contracted with a PBM, Express Scripts, Inc. ("ESI"), to administer TRICARE's mail order pharmacy programs. ESI has also administered TRICARE's retail pharmacy program since June 2004.

57. Similarly, TRICARE's military treatment facilities purchase medications through

procurement contracts with third party pharmaceutical prime vendors. When a TRICARE beneficiary submits an outpatient prescription to a military treatment facility's outpatient pharmacy, the pharmacy purchases the medication from the prime vendor pursuant to an existing procurement contract, and the drug is then dispensed to the patient.

58. While some physicians enroll in the TRICARE program as network or participating providers, any physician that is licensed, accredited and meets other standards of the medical community is authorized to provide services to TRICARE beneficiaries. Physicians who are enrolled in the TRICARE network must expressly certify their compliance with TRICARE's regulations. Yet all providers that provide services to TRICARE beneficiaries, whether network providers or non-participating providers, are required to comply with TRICARE's program requirements, including its anti-abuse provisions. 32 C.F.R.§ 199.9(a)(4). TRICARE regulations provide that claims submitted in violation of TRICARE's anti-abuse provisions can be denied. *Id.* § 199.9(b). Kickback arrangements are included within the definition of abusive situations that constitute program fraud. *Id.* §§ 199.2(b), 199.9(c)(12).

59. The statutes and regulations set forth above concerning Medicare, Medicaid, and TRICARE, when viewed together, state that healthcare providers must comply with the AKS in order for claims they cause to be submitted to these programs to be reimbursed. The claims submitted here for Cimzia violated the AKS in that these claims stemmed from prescriptions written by providers in exchange for bribes from Defendants while knowing that claims for reimbursement would be submitted to the above programs as a result. As such, and as more fully discussed below, the prescribing healthcare providers, expressly and impliedly, falsely certified compliance with the conditions of payment for, at least, Medicare, Medicaid, and TRICARE.

60. In addition to falsely certifying compliance with the AKS, the healthcare providers

referred to herein also falsely certified compliance with contractual provisions that were required conditions for payment.

61. As detailed herein, UCB devised and implemented schemes whereby it gave kickbacks to third party "educators" from RXC to induce providers to prescribe UCB's drug, Cimzia, and whereby Defendants provided free, in-kind support services to providers to induce those providers to prescribe Cimzia.

62. Knowingly paying kickbacks to induce physicians to prescribe a drug on-label or off-label (or to influence physician prescriptions) for individuals who seek reimbursement for the drug from a federal health care program or causing others to do so, while certifying compliance with the AKS (or while causing another to so certify), or billing the Government as if in compliance with these laws, violates the FCA and similar state False Claims Acts.

DEFENDANTS' FRAUDULENT SCHEMES

63. To unmask Defendants' unlawful conduct, Relator and its representatives conducted a rigorous, multi-part investigation that included interviews of numerous individuals with knowledge of and involvement in the schemes. The specific individuals whom Relator interviewed have direct knowledge with respect to the matters set forth herein during its investigation include:

- Witness A[2] – a sales representative for UCB from approximately June 2008 to April 2015 who promoted and sold Cimzia to prescribers;
- Witness B – a territory case manager for RXCrossroads since December 2011 who is now a supervisor for territory case managers;
- Witness C – a nurse educator for RXCrossroads since May 2015 who provides nurse education services for Cimzia primarily in Colorado;
- Witness D – a nurse educator for RXCrossroads since approximately 2013 who

[2] Witness information will be provided during discovery subject to a confidentiality order.

provides nurse education services for Cimzia primarily in Florida;

- Witness E – a case manager for RXCrossroads from approximately 2012 to 2013 who provided support services for Cimzia;
- Witness F – a sales representative for UCB from approximately June 2007 to May 2015 who promoted and sold Cimzia to prescribers;
- Witness G – a nurse educator for RXCrossroads from approximately 2007 to 2013 who provided nurse education services for Cimzia primarily in Michigan.

64. Relator has also conducted data analytics using a private healthcare data vendor that aggregates both public and private healthcare data. Through this vendor, Relator has access to and can analyze Medicare Part D prescription claims data, which provides information on prescription drugs, including Cimzia, prescribed by individual physicians and other health care providers that are paid for under the Medicare Part D Prescription Drug Program. Relator also has aggregated additional data from various state Medicaid providers. These data sources give Relator significant insight into prescription drug utilization over a multi-year period.

65. Through the investigation, Relator discovered Defendants' unlawful schemes to induce healthcare providers to write prescriptions for Cimzia by providing tangible, valuable benefits to healthcare providers in exchange for writing Cimzia prescriptions.

66. Cimzia is a brand-name prescription drug primarily used for the treatment of Crohn's Disease. Cimzia has other indications as well, including rheumatoid arthritis.

67. UCB sought to incentivize disease care providers to choose UCB's drug, Cimzia, over competitors' drugs. UCB identified the unique and particular needs and challenges that disease care providers faced in managing their practices and patients. Once these providers' needs and challenges were identified, UCB, through RXC, began offering these providers "solutions" to those needs and challenges if they prescribed UCB's drug.

68. In the first scheme, RXC contracted to provide UCB with a force of nurse educators

for Cimzia. UCB's Cimzia nurse educators are health care professionals who possess training, knowledge and experience in disease management, pre-disease care, and disease prevention. A nurse educator certification is "practice based" and requires health care professionals to gain professional experience working in the field.

69. Certified nurse educators are recognized as specialty clinicians with particular training, education and experience in disease education and care. Not surprisingly, nurse educators are in particular demand for providers who care for disease patients. Many nurse educators are employed by primary care and specialty practices to work with disease patients. As clinicians with significant training, education and experience, nurse educators can command significant compensation in the healthcare workforce.

70. In the second scheme, UCB induced providers to recommend its drug by offering and providing what is referred to as "reimbursement support" services through RXC, which included thousands of dollars of administrative services offered to providers for free.

71. Both of these schemes were design to induce providers to prescribe Cimzia, and UCB actively engages in and promotes these schemes. For example, one of UCB's area directors, Kurt Hughes, is "responsible for Managing seven (7) Area Business Specialists covering 23 States in the West;" "for In office Administration/injection of Cimzia to Gastroenterologists Rheumatologists for their Crohn's and Rheumatoid Arthritis patients;" and "for the corresponding benefits coverage, billing and coding of our in office injectable and coordination with MD and Practice Administrators and others responsible for the purchasing, coverage, billing and coding of our medicine" in the greater Denver area and the west coast region.

72. UCB designed and implemented these schemes to induce providers to prescribe Cimzia and increase its revenue. As one former Cimzia sales representative stated when he was

discussing his messaging to providers, "you just find the patients and we'll get them on the drugs."

A. *Quid Pro Quo* 1—Free Clinicians for Referrals

73. Relator's research determined that most prescribers typically allocate between 10 to 15 minutes to see routine patients. However, some patients, such as those suffering from Crohn's disease and rheumatoid arthritis, often require additional office time, training, follow-up, and additional resources to manage their disease. For these reasons, prescribers often rely on the services of highly skilled nursing staff – often called "nurse educators" – to help manage and treat these patients. The cost associated with the use of a nurse educator is significant, often requiring an annual salary that can exceed $60,000 or an hourly wage that can exceed $40.00 per hour.

74. Recognizing the additional needs associated with these patients, UCB developed a scheme whereby it would offer these nurse educators to providers at no charge if they would prescribe UCB's drug, Cimzia.

75. Specifically, UCB began offering and then providing these providers the time, service and expertise of an RXC employed nurse educator both to help manage that providers' disease patients and to provide disease training to the providers' staff. Of course, in typical *quid pro quo* fashion, in order to be given these services those providers would have to "support" (i.e., write prescriptions for) UCB's specific drug.

76. UCB's Cimzia nurse educator program is marketed using a branded term, "CIMplicity."[3] The CIMplicity website touts "Support made simple for *your practice* and your patients" (emphasis added) including "Nurse support" (i.e. Nurse Educators) and "Comprehensive reimbursement assistance" (i.e. reimbursement support services).[4] RXC also touts their "Field

[3] CIMplicity, http://cimziahcp.com/patient-support, (last visited December 27, 2016)
[4] *Id.*

Force" of "Nurse Educators" on their website.[5]

77. Once trained and deployed, these nurse educators began to provide free education services to any provider who would prescribe UCB's Cimzia. The RXC nurse educators were successful in saving prescribers time, money and resources and, in many instances, resulted in receiving higher reimbursement rates associated with certain disease care metrics. Not surprisingly, UCB's Cimzia sales have increased every year.

78. Relator interviewed two nurse educators employed by RXCrossroads who provided services for Cimzia and both agreed that their services save providers time and money. One nurse educator for RXCrossroads has provided nursed education services for Cimzia since May 2015 primarily in Colorado. The other nurse educator for RXCrossroads provided nurse education services for Cimiza from from approximately 2007 to 2013 in Michigan.

79. Likewise, a former Cimzia sales representative noted that he would promote these services to providers as a "free resource." He went on to say that he would talk to providers about how nurses could "go in there and eliminate some of the administrative burden and take that off their plate…"

80. When discussing how the provider no longer has to take the time to educate the patient, one nurse educator went on to state,"…don't sales reps give people – like doctors like tickets to games and stuff? I feel like that's a kickback. I feel like that's part of it. I feel like that extra training is like just another freebie for a physician – not to have to do the training." This nurse educator specifically noted that "they're prescribing medication without having to do any other work and getting kickback."

81. UCB recognized that having its own nurse educator interact directly with patients

[5] RXC Educators, https://www.rxcrossroads.com/OmnicareSCG/RXCrossroads/field-force, (last visited December 27, 2016)

also resulted in an increase in Cimzia refills and, thus, an increase in the revenue that these refills would provide. One nurse educator who provided education services for Cimzia stated that "adherence is dollars for the pharmaceutical industry…If they're adherent, they're refilling. Every time they refill their prescription, that's more dollars in the pharmaceutical company's pockets."

82. Two former UCB sales representatives confirmed they promoted these nurse education services as part of their sales pitch and strongly agreed that being able to promote the nurse educators helped them be successful in promoting Cimzia to potential prescribers.

83. One of the former sales representatives noted that he viewed nurse educators as an "extension of [his] efforts" because it was another resource who was in tune with what was going on in the provider's office.

84. The other former sales representative explained that being able to provide nurse educators helped "downstream" in the process and gave one example of a nurse educator being able to convince a patient to continue using Cimzia when the patient may not have otherwise continued with the drug. He stated that having a nurse educator involved resulted in higher success rates of patients getting on Cimzia and staying on Cimzia.

85. UCB providing educational and other services to providers in exchange for recommending its drug violates the AKS because it provides remuneration in the form of free nurse services to induce prescribers to prescribe UCB's drug. Prescribers receive a substantial benefit in utilizing these free nurse educators because they save time and money that they would have otherwise had to expend.

B. *Quid Pro Quo* 2—Free Reimbursement Experts for Referrals

86. UCB also induced providers to prescribe Cimzia by offering and providing what is referred to as "reimbursement support" services through RXC.

87. When a provider writes a prescription for Cimzia, a number of additional steps must be completed before the patient is able to "fill" the prescription at the pharmacy. These steps customarily include:

- Determining whether and to what extent the patient has prescription drug insurance benefits;
- Determining if the drug is on the formulary lists and, if so, the applicable tiers;
- Seeking a coverage determination for the drug from the patient's carrier;
- Determining the patient's co-pays and deductibles;
- Determining whether a patient may qualify for "co-pay" assistance or coupons;
- Appealing any denial of coverage or prior authorization;
- Determining the in-network pharmacy where the patient can have the drug filled; communicating this information to the patient; and managing the resultant paper trail.

88. These steps are time consuming, averaging roughly about 20 hours per week for a provider's office.[6] Completing these tasks requires the attention of the provider and/or the provider's staff, resulting in discrete economic costs to the provider.

89. For certain prescription drugs that are particularly expensive, like Cimzia, the provider's office must work with the patient's insurance carrier to obtain prior authorization for the drug. Prior authorization is the requirement that a prescriber obtain approval from the patient's health insurance plan before the drug can be dispensed by a pharmacy—or the patient may be required to pay for the medicine "out of pocket."

90. Because it entails advocacy on behalf of the patient, obtaining prior authorization

[6] *See* Christopher P. Morley, David J. Badolato, John Hickner, and John W. Epling, *The Impact of Prior Authorization Requirements on Primary Care Physicians' Offices: Report of Two Parallel Network Studies,* J. Am. Board Fam. Med. (January-February 2013), Vol. 26 no. 1, at 93-95.

is a responsibility that falls within the prescriber's duty of care.[7] Importantly, numerous states have enacted legislation that requires prescribers to obtain prior authorizations on behalf of the patients. *See, e.g.*, Ala. Medicaid Preferred Drug and Prior Authorization Program, Prior Authorization Criteria Instructions; Cal. Health and Safety Code, § 1367.241; 10 CCR 2505-10, § 8.017E; Delaware Health and Social Services General Policy, § 1.17; Florida Medicaid, Authorization Requirements Policy, §2-2.4.4 (June 2016); Georgia Dept. of Comm. Health Medicaid Fee-for-Service Pharmacy Prior Authorization Request Process Guide; Louisiana Medicaid Program Provider Manual, Chapter 37, § 37.5.5; Mass. Health Provider Manual, § 450.303; Mich. Dept. of Health and Human Servs., § 7.5; Minn. Statutes, § 62J.497, subd. 5; NY State Medicaid Program, Physician Prior Approval Guidelines; N.C. Dept. of Health and Human Servs., Prior Approval and Due Process; NJAC 10:51-1.14; Oregon Health Authority, Instructions for Submitting Prior Authorization Requests for Oregon Medicaid Providers (Aug. 2015); Pennsylvania Pharmacy Prior Authorization General Requirements; S.C. DHHS, Pharmacy Services Medicaid Provider Manual, § 2; Tenn. Medicaid Pharmacy Claims Submission Manual, § 7.6; Texas Admin. Code. Title 28, § 19.1820; Texas Admin. Code. Title 1 § 531.073; WV Health and Human Resources Bureau Manual, § 518.2.

91. Medicare, Medicaid, and TRICARE carriers also use the prior authorization process to contain costs associated with expensive medications. This is particularly true for products like Cimzia, which are expensive and come with a myriad of potential side-effects that

[7] *See* Getting Medical Pre-approval or Prior Authorization, *available at* https://www.cancer.org/treatment/finding-and-paying-for-treatment/understanding-health-insurance/managing-your-health-insurance/getting-medical-pre-approval-or-prior-authorization.html (noting that "Prior authorization is often used with expensive prescription drugs. It means that your doctor must explain that the drug is medically necessary before the insurance company will cover it. The company may want you to use a different medicine or try a different one before they will approve the one your doctor prescribes.").

may require other medications to manage. For such products, carriers routinely require prescribers to "make a case" of medical necessity and explain why a less expensive product is not an acceptable alternative. This process is designed to save taxpayer dollars by ensuring that the more expensive medications are prescribed only when needed.

92. As a coalition of healthcare organizations led by the American Medical Association has recognized, coverage determinations, prior authorization, and appeals often entail "very manual, time-consuming processes . . . [that can] divert valuable and scarce resources away from direct patient care."[8] Further, industry research demonstrates that these tasks are time-consuming and costly for prescribers. For instance, a study of 12 primary care practices published in 2013 in The Journal of the American Board of Family Medicine concluded that "preauthorization is a measurable burden on physician and staff time."[9]

93. According to another study published in 2009 in Health Affairs, primary care prescribers spent a mean of 1.1 hours per week on authorization-related work, primary care nursing staff spent 13.1 hours, and primary care clerical staff spent 5.6 hours.[10] The same study estimated that the overall cost to the healthcare system of all practice interactions with health plans, including authorizations, was between $23 billion and $31 billion annually.

94. Alternatively, if a prescriber does not wish to pay its own staff to carry out these administrative tasks, prescribers can outsource them to third-party commercial vendors for a fee.

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[8] *See Prior Authorization and Utilization Management Reform Principles, available at* https://www.ama-assn.org/sites/default/files/media-browser/principles-with-signatory-page-for-slsc.pdf.

[9] *See* Morley, *supra* at 93.

[10] *See id.* at 95 (citing Lawrence P. Casalino, Sean Nicholson, David N. Gans, Terry Hammons, Dante Morra, Theodore Karrison, Wendy Levinson, *What Does It Cost Physician Practices To Interact With Health Insurance Plans?*, Health Affairs (July-August 2009), Vol. 28 no. 4, at 533-43).

Numerous vendors provide these outsourcing services. As a study conducted by Deloitte on behalf of a large pharmaceutical company demonstrates, medical practices pay up to $98 per initial insurance verification, up to $75 for insurance re-verification, up to $111.82 for prior authorizations, and other à la carte fees.

Activities	Lash	McKesson	Covance	Incumbent Average
Re-verfication	$20.75	$75.00	$50.00	$41.53
Insurance Verification	$98.00	$75.00	$75.00	$88.50
Reimbursement Support - Rate Verification	$68.00	$65.00	$0.00	$62.52
Coding & Reimbursement Assistance	$20.75	$30.00	$12.45	$23.43
Claims Support and Appeals	$104.28	$125.00	$57.78	$108.45
Ad Hoc Support and Consulting	$100.00	$100.00	$1.00	$93.54
Co-Pay Card Program Administration	$1.00	$0.00	$1.00	$0.65
Field Reimbursement Services	$19,180.00	$10,000.00	$1.00	$14,736.15
Site Visit/ Telecon	$2,150.00	$100.00	$1.00	$1,296.80
General Inquiry	$20.75	$15.00	$12.45	$18.21
Injection Network and Location Support	$104.28	$30.00	$12.45	$72.45
Sales Portal	$5,000.00	$100.00	$45,000.00	$5,904.35
Provider Portal	$8,000.00	$2.50	$0.00	$4,696.52
Plan Comparison	$20.75	$125.00	$88.65	$61.44
Send Hotline Material	$0.60	$15.00	$12.45	$6.38
Benefit Summary Call	$0.00	$100.00	$0.00	$34.78
PAP Prescreening and Referrals	$62.00	$30.00	$89.65	$52.67
Prescription Triage	$68.00	$100.00	$12.45	$75.51
Prior Authorization	$68.00	$75.00	$111.82	$73.29
Injection Reminder	$21.00	$15.00	$12.45	$18.36
Analytics and Reporting	$110.00	$100.00	$135.00	$108.15
Sales Rep Hotline	$20.75	$15.00	$12.45	$18.21
Sample/Vouchers	$100.00	$30.00	$12.45	$69.94
CSR Training and On-boarding	$0.00	$100.00	$0.00	$34.78
Language Line	$0.00	$100.00	$1.00	$34.85
Telecommunications	$0.40	$100.00	$1.00	$35.08

95. Thus, whether outsourced or performed in-house, the tasks that must be completed before prescriptions are filled result in significant, tangible administrative costs to prescribers. These are direct costs that prescribers would have to incur in performing the tasks or in outsourcing the burdensome administrative tasks associated with support services.

96. Despite the significant costs associated with support services, prescribers are not allowed to charge the patient or their insurance provider for these tasks.[11] Thus, when an office-based prescriber receives payment for an office consultation, the payment is intended to compensate the prescriber for medical care given and administrative tasks associated with that patient's care.[12] These tasks include support services.

97. UCB was undoubtedly very aware of the time and cost associated with performing these services and chose to incentivize prescribers to choose its drug over other drugs by assuming the responsibility and expense for these support services.

98. One of UCB's field reimbursement managers in Birmingham, Alabama, Chris Connell, provides reimbursement consultation for Cimzia to Rheumatology & GI practices and internal stakeholders including: benefits verification, claims filing & denials, prior authorization, coding, claims tracking & patient support services for accounts in AL, MS, LA, TN, GA, FL, KY.

99. UCB drug representatives' pitch to providers in this regard has essentially been as follows:

> *Dear Doctor: If you prescribe our drug (i.e., "recommend" the patient to use our drug), we will give you the services and*

[11] For example, in Texas, "[p]roviders must certify that no charges beyond reimbursement paid under Texas Medicaid for covered services have been, or will be, billed to an eligible client." The Texas Medicaid Provider Procedures Manual makes clear to providers that "Federal regulations prohibit providers from charging clients a fee for completing or filing Medicaid claim forms" and notes that the "cost of claims filing is part of the usual and customary rate for doing business." Further, providers cannot charge "Texas Medicaid clients, their family, or the nursing facility for telephone calls, telephone consultations, or signing forms." Texas Medicaid Provider Procedures Manual § 1.6.9 (Dec. 2017), *available at* http://www.tmhp.com/Pages/Medicaid/Medicaid_Publications_Provider_manual.aspx (last accessed, Dec. 20, 2017).

[12] The technical term for an office visit is "evaluation and management services" or "E/M." In 2012, the most commonly billed Medicare physician service was the $70 "doctor office visit" for a 15-minute consultation, closely followed by the $100 "doctor office visit" for a 30-minute consultation. Medicare pays over $11 billion each year for E/M services alone. Medicaid and private insurers also pay billions each year.

> *resources of a full reimbursement support team to manage the process associated with prescribing the drug. This service will save you the cost and expenses normally associated with managing a patient's prescription and make your practice more profitable.*

100. This value proposition was a powerful tool in the hands of UCB's drug representatives and used to influence providers to recommend and prescribe UCB's Cimzia. UCB's drug representatives could offer a provider an "on call" reimbursement support team to manage the patient's UCB drug prescriptions. Reimbursement support services became very much a part of the UCB drug representatives' collective sales pitch.

101. One former UCB sales representative who promoted and sold Cimzia described incentivizing prescribers as follows: "Doctor, we are going to work with you from the time you put a patient on a product, for the patient's setup and home injection, we are going to help you every step of the way. That will include a benefits investigation of the patient's insurance, co-pay support, patient assistance program for your indigent patients, appeals assistance, letters of medical necessity, nurse educator support, injection training, drug disposal, travel carry kits, nurse hotline. All those things are important so the physician understands that they are not going alone…with this prescription which is expensive, time consuming, and you know, in general is a pain in my rear end. So if you can help me with that, I'm interested in talking to you."

102. This same sales representative stated that offering these services "can be a real influencer on a prescriber."

103. That is, rather than promoting and marketing its drug based on patient outcomes and efficacy, UCB introduced an additional incentive to providers to recommend its drug to patients. UCB knew that this service would present a tangible value to the providers. When that offer was accepted, the provider received the benefits of the reimbursement support service without actually having to pay for those services.

104. Most importantly, these services resulted in greater profit from each provider's evaluation and management unit charge. It was in this fashion, giving a provider free reimbursement support services, that UCB "eliminate[d] an expense that [the provider] would have otherwise incurred"[13] if the provider would have had to perform the tasks or pay to outsource these tasks associated with the prescription drug. Such "in kind" remuneration given to induce a recommendation for a UCB drug is an unlawful kickback under the AKS.

105. In 2012-2013, a case manager for RXCrossroads, Barbara Robinson, in Jeffersonville, Indiana provided full detailed benefit investigations for Cimizia, which included contacting insurance company, pharmacy benefit manager and specialty pharmacy; and checking eligibility deductible out of pocket expenses for patients enrolled in the Cimplicity Cimzia

106. Another case manager for RXCrossroads interviewed by Relator estimated that a normal benefit investigation could last anywhere from 45 minutes to two or three hours depending on hold times and knowledge of the insurance representative. Prior authorization for Cimzia could likewise take anywhere from 15 minutes to half an hour, while a coverage appeal could last from an hour to a span of several days. The case manager estimated that a prescriber's office would have to provide a salary of at least $40,000 per year just to provide these services. Another case manager estimated that prescriber's office would pay approximately $17 per hour to have someone handle these services in office.

107. A territory case manger for RXCrossroads, Jennifer Watson, in Louisville, Kentucky from 2011-2014 described her duties as follows:

> Managed a group of 5 people. Provided case management for key accounts within a territory. Managed Kentucky, Indiana, Ohio, and Michigan as well as managed key accounts in Washington,

[13] Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003) ("CPG") Section II (2), such service is a suspect remuneration as it "eliminate[d] an expense that the physician would have otherwise incurred (i.e., have independent value to the physician)".

> Tennessee, Florida, and Texas. Ensured that patients were on paid therapy, reported back to the territory sales representatives of patients that were on paid therapy. Assisted sales representatives in the field educating the physician offices on Cimzia therapy, how I could assist, how I could manage patient therapy, and initiate prior authorizations on their behalf. Followed up with patients, sales representatives, district managers, physician offices and specialty pharmacies to ensure therapy was being managed, shipments were being delivered, and that the territory goals were being met. Verified insurance coverage with patient's insurance carriers, obtained the coverage necessary, assisted with copay assistance as needed, combined together in a summary of benefits package that was submitted to the physicians office on behalf of patient. Assisted with quality assurance of peers, helping build account knowledge. Held the number one Crohn's district for 2 years in a row.

108. Defendants, thus, provided an extremely valuable benefit to the prescribers' offices that utilized their services for Cimzia as one RXCrossroads Cimzia case manager noted: "It is a very very big time saver, cost save for them because they can see multiple patients regarding their illnesses and their specialty that they're providing versus doing benefit investigation."

109. This same case manager further recognized: "We have more doctors prescribing the medication simply because they know that there are services that go hand in hand with it." She confirmed that she saw an increase in prescriptions for Cimzia from a provider after utilizing the reimbursement support services.

110. Within the pharmaceutical industry, RXC openly promotes the nature of the services it offers to pharmaceutical companies and boasts that its services will increase a pharmaceutical company's drug sales. As one of the RXC Cimzia territory case managers confirmed, they provide a benefit to the doctors, which benefits the manufacturers.

111. Here, Defendants gave providers an *a la carte* single point of contact person to manage the UCB prescription process, which greatly reduced and/or eliminated the providers' overhead and expenses that would otherwise have been associated with any UCB prescription.

112. The reimbursement support services provided a significant value to providers because it eliminated the time and expense of determining and verifying patients' insurance benefits, determining whether a prescribed drug was on formulary and determining co-pays and deductibles. Reimbursement support services also saved providers' staff time because RXC would manage each step and communicate with the patient directly.

113. Through RXC, providers could also eliminate the time and expense of appealing a denial of benefits and the cumbersome prior authorization process. Finally, providers no longer needed to manage a patient's call for refills or additional authorizations, as RXC managed this function as well.

114. By giving a provider reimbursement support services, Defendants gave a tangible "in kind" benefit to providers that greatly reduced, and in some instances eliminated, a provider's administrative costs related to prescribing UCB's drug, Cimzia, and thus induced providers to choose Cimzia over a competitor's drugs.

DAMAGES

115. Defendants' schemes and kickback violations resulted in the submission of numerous false claims to government programs.

116. As Defendants profited from the illegal schemes described herein, Medicare and Medicaid and other government health care programs were made to bear the costs. From 2011 to the present, Defendants' actions knowingly have caused pharmacies, Part D sponsors, Fiscal Intermediaries and others to submit millions of dollars in claims to Medicare and Medicaid for UCB's Cimzia that were provided to beneficiaries as a result of Defendants' illegal *quid pro quo* arrangements. Those false claims have caused Medicare and Medicaid and other government

health care programs to disburse tens of millions of dollars in reimbursements that should not have been paid.

117. Relators' investigation identified specific providers who were targeted with nurse educators and reimbursement support services in exchange for prescribing UCB's drug, Cimzia, and examples of claims submitted from these providers.

118. Exhibit A contains specific examples of Cimzia Medicare claims data corresponding to those individuals identified in Relators' investigation as being targeted with these *quid pro quo* services in exchange for Cimzia prescriptions.

119. These specific claims are linked to the Defendants' conduct alleged herein because each claim resulted from a prescription written by a prescriber who was offered and/or received unlawful remuneration under the nurse educator program. This unlawful remuneration saved the prescribers and their staff time, resources, and money that the prescriber would otherwise have had to incur to provide follow-up care and monitoring for patients treating with Cimzia.

120. These specific claims are further linked to the Defendants' conduct alleged herein because each claim resulted from a prescription written by a prescriber who was offered and/or received unlawful remuneration under the support services program. This unlawful remuneration saved the prescribers and their staff time, resources, and money that the prescriber would otherwise have had to incur to perform administrative tasks necessary for the patients to receive treatment with Cimzia.

121. Given the breadth of Defendants' misconduct and the large volume of claims submitted to government programs, it is statistically impossible that Defendants' conduct did not result in the submission of false claims. Claims were submitted to federal and state healthcare programs, including Medicare and Medicaid, in most, if not all, states for Cimzia. Given that the

marketing schemes described herein were actively promoted by UCB and widely used by prescribers, it is statistically impossible that claims for Cimzia were not submitted to Government programs.

122. Further, upon information and belief, Defendants were specifically targeting government programs. One former Cimzia sales representative mentioned UCB using data from its reimbursement support services program to identify the percentage of the Medicare market that they are capturing.

NO SAFE HARBOR

123. The safe harbor provided for personal services business arrangements under certain circumstances does not apply to any of Defendants' actions or arrangements pleaded in this Complaint for at least the following reasons: First, Defendants' agency agreement does not cover all of the services RXC provides and/or specify the services to be provided by RXC, or the agreement seeks to contract for the illegal activity described in this Complaint, rendering it void *ab initio*. Second, the compensation UCB paid to the RXC nurse educators was not set in advance and is determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other federal health care programs. Third, the services performed under the agreement involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law. Fourth, the aggregate services contracted for exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

SUMMARY

124. As detailed above, the Defendants are liable for damages based on the Government's payment of all claims submitted to federal health care programs for prescriptions written for UCB's Cimzia beginning from the time they began paying remuneration up and through the present because the claims were the result of recommendations induced, in whole or in part, by remuneration.

125. Compliance with the AKS is a precondition of payment by virtue of federal and state statutes, regulations, provider agreements, and contracts.

126. The certifications and attestations signed by physicians, pharmacies, PBMs and Part D sponsors certified compliance with the AKS. Kickbacks that were paid to and received by physicians and other health care professionals to recommend Cimzia as alleged herein rendered those certifications and attestations false. Those false statements were material to the false claims submitted for Cimzia.

127. Claims for UCB's Cimzia arising from the kickbacks expressly and impliedly misrepresent compliance with a material condition of payment, to wit, compliance with the AKS. Claims that include items or services resulting from a violation of the AKS constitute false or fraudulent claims under the AKS. 42 U.S.C. §§ 1320a-7a(7) and 1320a-7b(b) and 1320a-7b(g).

128. By providing remuneration to physicians and other health care professionals, UCB intended to induce those physicians and other health care professionals to recommend and/or prescribe UCB's Cimzia.

129. It was reasonably foreseeable that some of those prescriptions would be for federal health care program beneficiaries and that claims for those prescriptions would be submitted to

federal health care programs. Thousands of such prescriptions or claims based on such prescriptions were, in fact, submitted to and paid for by federal health care programs.

COUNTS

FIRST COUNT – AGAINST ALL DEFENDANTS
For Violations of the False Claims Act:
Presenting False Claims for Payment (31 U.S.C. § 3729(a)(1)(A))

130. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

131. Relator seeks relief against Defendants under Section 3729(a)(1)(A) of the FCA, 31 U.S.C. § 3729(a)(1)(A).

132. As a result of UCB's offering or paying, and UCB's co-Defendants, physicians, and other health care professionals soliciting or receiving, kickbacks to purchase, order, or recommend the purchasing or ordering of UCB's drug, Cimzia, in violation of the federal AKS, 42 U.S.C. § 1320a-7b(b)(1) and (b)(2), Defendants caused false and fraudulent claims for payment to be presented to federal health care programs.

133. Accordingly, Defendants knowingly caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

134. By reason of the false or fraudulent claims that Defendants knowingly caused to be presented to federal health care programs, the United States has been damaged in a substantial amount to be determined at trial and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

SECOND COUNT – AGAINST ALL DEFENDANTS
For Violations of the False Claims Act:
Use of False Statements (31 U.S.C. § 3729(a)(1)(B))

135. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

136. Relator seeks relief against Defendants under Section 3729(a)(1)(B) of the FCA, 31 U.S.C. § 3729(a)(1)(B).

137. As a result of UCB's offering or paying, and UCB's co-Defendants, physicians, and other health care professionals soliciting or receiving, kickbacks to purchase, order, or recommend purchasing or ordering UCB's drug, Cimzia, in violation of the federal AKS, 42 U.S.C. § 1320a-7b(b)(1) and (b)(2), Defendants knowingly caused pharmacies, PBMs, Part D sponsors, fiscal intermediaries, and others to make false records or statements that were material to getting false or fraudulent claims paid by federal health care programs.

138. More specifically, the pharmacies, PBMs, Part D sponsors, fiscal intermediaries, and others, falsely certified, and/or represented that the reimbursements they sought for UCB's drug, Cimzia, were in full compliance with applicable federal and state laws prohibiting fraudulent and false reporting, including but not limited to the AKS. Those false certifications, statements, or representations caused federal health care programs to pay out sums that would not have been paid if those programs had been made aware of the falsity of the certifications, statements, or representations.

139. Accordingly, Defendants caused the use of false records or statements material to false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(B).

140. By reason of these false records or statements, the United States has been damaged in a substantial amount to be determined at trial, and is entitled to treble damages plus a monetary civil penalty for each false record or statement.

THIRD COUNT – AGAINST ALL DEFENDANTS
For Violations of the False Claims Act:
Conspiring to Violate the False Claims Act (31 U.S.C. § 3729(a)(1)(C))

141. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

142. Relator seeks relief against Defendants under Section 3729(a)(1)(C) of the FCA, 31 U.S.C. § 3729(a)(1)(C).

143. As set forth above, UCB conspired with UCB's co-Defendants, physicians, and other health care professionals to offer or pay kickbacks in exchange for, or to induce them to purchase, order, or recommend the purchasing or ordering of UCB's drug, Cimzia, in violation of the federal AKS, 42 U.S.C. § 1320a-7b(b)(1) and (b)(2), thereby causing false and fraudulent claims to be presented to federal health care programs seeking reimbursement for UCB's drug, Cimzia, dispensed in connection with the kickback scheme.

144. Accordingly, Defendants conspired to commit violations of 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B), in violation of 31 U.S.C. § 3729(a)(1)(C).

145. By reason of the Defendants' conspiracy to violate 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B), the United States has been damaged in a substantial amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

FOURTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the California False Claims Act
Cal. Gov't Code §§ 12650 – 12656

146. This is a claim for treble damages and civil penalties under the California False Claims Act, Cal. Gov't Code §§ 12650 – 12656. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

147. Defendants violated the California False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of California as described herein.

148. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of California.

149. The State of California, unaware of the false or fraudulent nature of these claims, paid such claims which the State of California would not otherwise have paid.

150. By reason of these payments, the State of California has been damaged, and continues to be damaged, in a substantial amount.

FIFTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Colorado Medicaid False Claims Act
Col. Rev. Stat. Ann. §§ 25.5-4-303.5 – 25.5-4-310

151. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act, Colo. Rev. Stat. Ann. §§ 25.5-4-303.5 – 25.5-4-310. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

152. Defendants violated the Colorado Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Colorado, as described herein.

153. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Colorado.

154. The State of Colorado, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Colorado would not otherwise have paid.

155. By reason of these payments, the State of Colorado has been damaged, and continues to be damaged, in a substantial amount.

SIXTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Connecticut False Claims And Other Prohibited Acts Under State-Administered Health or Human Services Act ("Connecticut False Claims Act")
Conn. Gen. Stat. Ann. §§ 4-274-4-289.

156. This is a claim for treble damages and civil penalties under the Connecticut False Claims Act, Conn. Gen. Stat. Ann. §§ 4-274-4-289. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

157. Defendants violated the Connecticut False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Connecticut, as described herein.

158. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Connecticut.

159. The State of Connecticut, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Connecticut would not otherwise have paid.

160. By reason of these payments, the State of Connecticut has been damaged, and continues to be damaged, in a substantial amount.

SEVENTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Delaware False Claims and Reporting Act
Del. Code Ann. Tit. 6, §§ 1201 – 1211

161. This is a claim for treble damages and civil penalties under the Delaware False Claims and Reporting Act, Del. Code Ann. Tit. 6, §§ 1201 – 1211. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

162. Defendants violated the Delaware False Claims and Reporting Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Delaware, as described herein.

163. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Delaware.

164. The State of Delaware, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Delaware would not otherwise have paid.

165. By reason of these payments, the State of Delaware has been damaged, and continues to be damaged, in a substantial amount.

EIGHTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act of 2012
D.C. Code Ann. §§ 2-381.01 – 2-381.10

166. This is a claim for treble damages and civil penalties under the District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act, D.C. Code Ann. §§ 2-381.01 – 2-381.10. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

167. Defendants violated the District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act by engaging in the fraudulent and illegal practices described herein,

including knowingly causing false claims to be presented to the District of Columbia, as described herein.

168. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the District of Columbia.

169. The District of Columbia, unaware of the false or fraudulent nature of these claims, paid such claims which the District of Columbia would not otherwise have paid.

170. By reason of these payments, the District of Columbia has been damaged, and continues to be damaged, in a substantial amount.

NINTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Florida False Claims Act
Fla. Stat. Ann. §§ 68.081 – 68.092

171. This is a claim for treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 – 68.092. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

172. Defendants violated the Florida False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Florida as described herein.

173. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Florida.

174. The State of Florida, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Florida would not otherwise have paid.

175. By reason of these payments, the State of Florida has been damaged, and continues to be damaged, in a substantial amount.

TENTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Georgia False Medicaid Claims Act
Ga. Code Ann. §§ 49-4-168 – 49-4-168.6

176. This is a claim for treble damages and civil penalties under Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 – 49-4-168.6. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

177. Defendants violated the Georgia State False Medicaid Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Georgia, as described herein.

178. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Georgia.

179. The State of Georgia, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Georgia would not otherwise have paid.

180. By reason of these payments, the State of Georgia has been damaged, and continues to be damaged, in a substantial amount.

ELEVENTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Hawaii False Claims Act for False Claims to the State
Haw. Rev. Stat. §§ 661-21 – 661-31

181. This is a claim for treble damages and civil penalties under the Hawaii False Claims Act for False Claims to the State, Haw. Rev. Stat. §§ 661-21 – 661-31. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

182. Defendants violated the Hawaii False Claims Acts for False Claims to the State by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Hawaii, as described herein.

183. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Hawaii.

184. The State of Hawaii, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Hawaii would not otherwise have paid.

185. By reason of these payments, the State of Hawaii has been damaged, and continues to be damaged, in a substantial amount.

TWELFTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Illinois False Claims Act
740 Ill. Comp. Stat. Ann. §§ 175/1 – 175/8

186. This is a claim for treble damages and civil penalties under the Illinois False Claims Act, 740 Ill. Comp. Stat. Ann. §§ 175/1 – 175/8. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

187. Defendants violated the Illinois False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Illinois, as described herein.

188. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Illinois.

189. The State of Illinois, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Illinois would not otherwise have paid.

190. By reason of these payments, the State of Illinois has been damaged, and continues to be damaged, in a substantial amount.

THIRTEENTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Indiana False Claims and Whistleblowers Protection Act
Ind. Code Ann. §§ 5-11-5.5-1 – 5-11-5.5-18

191. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblowers Protection Act, Ind. Code Ann. §§ 5-11-5.5-1 – 5-11-5.5-18. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

192. Defendants violated the Indiana False Claims and Whistleblowers Protection Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Indiana, as described herein.

193. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Indiana.

194. The State of Indiana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Indiana would not otherwise have paid.

195. By reason of these payments, the State of Indiana has been damaged, and continues to be damaged, in a substantial amount.

FOURTEENTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Iowa False Claims Act
Iowa Code Ann. §§ 685.1 – 685.7

196. This is a claim for treble damages and civil penalties under the Iowa False Claims Act, Iowa Code Ann. §§ 685.1- 685.7. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

197. Defendants violated the Iowa False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Iowa, as described herein.

198. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Iowa.

199. The State of Iowa, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Iowa would not otherwise have paid.

200. By reason of these payments, the State of Iowa has been damaged, and continues to be damaged, in a substantial amount.

FIFTEENTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. §§ 437.1 – 440.16

201. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §§ 437.1 – 440.16. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

202. Defendants violated the Louisiana Medical Assistance Programs Integrity Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Louisiana, as described herein.

203. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Louisiana.

204. The State of Louisiana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Louisiana would not otherwise have paid.

205. By reason of these payments, the State of Louisiana has been damaged, and continues to be damaged, in a substantial amount.

SIXTEENTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Massachusetts False Claims Law
Mass. Gen. Laws Ann. Ch. 12 §§ 5A – 5O

206. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Law, Mass. Gen. Laws Ann. Ch. 12, §§ 5A – 5O. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

207. Defendants violated the Massachusetts False Claims Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the Commonwealth of Massachusetts, as described herein.

208. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth of Massachusetts.

209. The Commonwealth of Massachusetts, unaware of the false or fraudulent nature of these claims, paid such claims which the Commonwealth of Massachusetts would not otherwise have paid.

210. By reason of these payments, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in a substantial amount.

SEVENTEENTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Michigan Medicaid False Claims Act
Mich. Comp. Laws Ann. §§ 400.601 – 400.615

211. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claims Act, Mich. Comp. Laws Ann. §§ 400.601 – 400.615. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

212. Defendants violated the Michigan Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Michigan, as described herein.

213. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Michigan.

214. The State of Michigan, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Michigan would not otherwise have paid.

215. By reason of these payments, the State of Michigan has been damaged, and continues to be damaged, in a substantial amount.

EIGHTEENTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Minnesota False Claims Act
Minn. Stat. Ann. §§ 15C.01 – 15C.16

216. This is a claim for treble damages and civil penalties under the Minnesota False Claims Act, Minn. Stat. Ann. §§ 15C.01 – 15C.16. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

217. Defendants violated the Minnesota False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Minnesota, as described herein.

218. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Minnesota.

219. The State of Minnesota, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Minnesota would not otherwise have paid.

220. By reason of these payments, the State of Minnesota has been damaged, and continues to be damaged, in a substantial amount.

NINETEENTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Montana False Claims Act
Mont. Code Ann. §§ 17-8-401 – 17-8-416

221. This is a claim for treble damages and civil penalties under Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 – 17-8-416. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

222. Defendants violated the Montana False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Montana, as described herein.

223. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Montana.

224. The State of Montana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Montana would not otherwise have paid.

225. By reason of these payments, the State of Montana has been damaged, and continues to be damaged, in a substantial amount.

TWENTIETH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Nevada Submission of False Claims to State or Local Government Act
Nev. Rev. Stat. Ann. §§ 357.010 – 357.250

226. This is a claim for treble damages and civil penalties under the Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. §§ 357.010 – 357.250. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

227. Defendants violated the Nevada Submission of False Claims to State or Local Government Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Nevada, as described herein.

228. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Nevada.

229. The State of Nevada, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Nevada would not otherwise have paid.

230. By reason of these payments, the State of Nevada has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-FIRST COUNT– AGAINST ALL DEFENDANTS
For Violations of the New Jersey False Claims Act
N.J. Stat. Ann. §§ 2A:32C-1 – 2A:32C-18

231. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 – 2A:32C-18. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

232. Defendants violated the New Jersey False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Jersey, as described herein.

233. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Jersey.

234. The State of New Jersey, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Jersey would not otherwise have paid.

235. By reason of these payments, the State of New Jersey has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-SECOND COUNT– AGAINST ALL DEFENDANTS
For Violations of the New Mexico Medicaid False Claims Act
N.M. Stat. Ann. §§ 27-14-1 – 27-14-15

236. This is a claim for treble damages and civil penalties under the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 – 27-14-15. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

237. Defendants violated the New Mexico Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Mexico, as described herein.

238. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Mexico.

239. The State of New Mexico, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Mexico would not otherwise have paid.

240. By reason of these payments, the State of New Mexico has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-THIRD COUNT– AGAINST ALL DEFENDANTS
For Violations of the New Mexico Fraud Against Taxpayers Act
N.M. Stat. Ann. §§ 44-9-1 – 44-9-14.

241. This is a claim for treble damages and civil penalties under the New Mexico Fraud Against Taxpayers False Claims Act, N.M. Stat. Ann. §§ 44-9-1 – 44-9-14. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

242. Defendants violated the New Mexico Fraud Against Taxpayers False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Mexico, as described herein.

243. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Mexico.

244. The State of New Mexico, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Mexico would not otherwise have paid.

245. By reason of these payments, the State of New Mexico has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-FOURTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the New York False Claims Act
N.Y. Fin. Law §§ 187 – 194

246. This is a claim for treble damages and civil penalties under the New York False Claims Act, N.Y. Fin. Law §§ 187 – 194. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

247. Defendants violated the New York False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New York, as described herein.

248. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New York.

249. The State of New York, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New York would not otherwise have paid.

250. By reason of these payments, the State of New York has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-FIFTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the North Carolina False Claims Act
N.C. Gen. Stat. Ann. §§ 1-605 – 1-618

251. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, N.C. Gen. Stat. Ann. §§ 1-605 – 1-618. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

252. Defendants violated the North Carolina False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of North Carolina, as described herein.

253. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of North Carolina.

254. The State of North Carolina, unaware of the false or fraudulent nature of these claims, paid such claims which the State of North Carolina would not otherwise have paid.

255. By reason of these payments, the State of North Carolina has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-SIXTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Oklahoma Medicaid False Claims Act
Okla. Stat. Ann. Tit. 63, §§ 5053 – 5054

256. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, Okla. Stat. Ann. Tit. 63, §§ 5053 – 5054. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

257. Defendants violated the Oklahoma Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Oklahoma, as described herein.

258. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Oklahoma.

259. The State of Oklahoma, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Oklahoma would not otherwise have paid.

260. By reason of these payments, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-SEVENTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Rhode Island State False Claims Act
R.I. Gen. Laws Ann. §§ 9-1.1-1 – 9-1.1-9

261. This is a claim for treble damages and civil penalties under the Rhode Island State False Claims Act, R.I. Gen. Laws Ann. §§ 9-1.1-1 – 9-1.1-9. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

262. Defendants violated the Rhode Island State False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Rhode Island, as described herein.

263. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Rhode Island.

264. The State of Rhode Island, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Rhode Island would not otherwise have paid.

265. By reason of these payments, the State of Rhode Island has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-EIGHTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Tennessee False Claims Act
Tenn. Code Ann. §§ 4-18-101 – 4-18-108 And
For Violations of the Tennessee Medicaid False Claims Act
Tenn. Code Ann. §§ 71-5-181 – 71-5-185

266. This is a claim for treble damages and civil penalties under the Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101 – 4-18-108 and the Tennessee Medicaid False Claims Act, Tenn. Code. Ann. §§ 71-5-181 – 71-5-185. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

267. Defendants violated the Tennessee False Claims Act and the Tennessee Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Tennessee, as described herein.

268. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Tennessee.

269. The State of Tennessee, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Tennessee would not otherwise have paid.

270. By reason of these payments, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-NINTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. §§ 36.001 – 36.132

271. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 – 36.132. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

272. Defendants violated the Texas Medicaid Fraud Prevention Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Texas, as described herein.

273. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Texas.

274. The State of Texas, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Texas would not otherwise have paid.

275. By reason of these payments, the State of Texas has been damaged, and continues to be damaged, in a substantial amount.

THIRTIETH– AGAINST ALL DEFENDANTS
For Violations of the Virginia Fraud Against Taxpayers Act
Va. Code Ann. §§ 8.01-216.1 – 8.01-216.19

276. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 – 8.01-216.19. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

277. Defendants violated the Virginia Fraud Against Taxpayers Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the Commonwealth of Virginia, as described herein.

278. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth of Virginia.

279. The Commonwealth of Virginia, unaware of the false or fraudulent nature of these claims, paid such claims which the Commonwealth of Virginia would not otherwise have paid.

280. By reason of these payments, the Commonwealth of Virginia has been damaged, and continues to be damaged, in a substantial amount.

THIRTY-FIRST COUNT– AGAINST ALL DEFENDANTS
For Violations of the Washington Medicaid Fraud False Claims Act
Wash. Rev. Code Ann. §§ 74.66.005 – 74.66.130

281. This is a claim for treble damages and civil penalties under the Washington Medicaid Fraud False Claims Act, Wash. Rev. Code Ann. §§ 74.66.005 – 74.66.130. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

282. Defendants violated the Washington Medicaid Fraud False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Washington, as described herein.

283. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Washington.

284. The State of Washington, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Washington would not otherwise have paid.

285. By reason of these payments, the State of Washington has been damaged, and continues to be damaged, in a substantial amount.

PRAYER FOR RELIEF

WHEREFORE, Relator requests that judgment be entered against Defendants as follows:

(a) treble the Government's damages in an amount determined at trial, plus the maximum statutorily-allowed penalty for each false claim submitted in violation of the FCA or State statute set forth above;

(b) the applicable administrative civil penalties for each violation of the AKS and State-equivalent statute, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited or received, without regard to whether a portion of that amount was offered, paid or received for a lawful purpose;

(c) an award of costs and the maximum Relator award allowed pursuant to the FCA and State statutes set forth above; and

(d) such further relief as is proper.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38, Relator hereby demands trial by jury.

Dated this the 14th day of May, 2019.

/s/ C. Lance Gould
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CERTIFICATE OF SERVICE

I certify that I caused this document filed through the ECF system to be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF), and paper copies will be sent to those indicated as non-registered participants.

Dated: May 14, 2019 By: /s/ C. Lance Gould
C. LANCE GOULD